REMARKS

The amendments to the claims are all supported by the original claims. Support for new claim 11 is found in the original specification at page 16, lines 26-34.

Claims 1 and 3-6 have been rejected under the second paragraph of 35 USC § 112 as being indefinite. This rejection is respectfully traversed.

All of the recitations of multiple ranges have been eliminated from the claims by amendment. The "where appropriate" recitation has been replaced by the conventional "optionally."

Claims 1-8 have been rejected under 35 USC § 103(a) as being unpatentable over Breitenbach et al., US 6,221,638 (Breitenbach). This rejection is respectfully traversed.

Although Breitenbach discloses lipoic acid in a very broad listing of "active ingredients" it is not mentioned anywhere else again in the reference. It is noticeably absent from the list of materials for which the process disclosed is said to be suitable (col. 6, lines 59 *et seq.*) although others of the compounds having vitamin B properties are specifically listed. In other words, although lipoic acid is disclosed as a material having vitamin B properties, it is not disclosed as being suitable for the disclosed process.

Breitenbach discloses compositions having active ingredients within the range of 0.1 to 95% by weight (col. 6, lines 40-44). However, as disclosed in the instant specification, lipoic acid has plasticizing properties so that the glass transition

temperature of a mixture containing it falls as the lipoic acid content increases. The purpose of the Breitenbach disclosure is to produce "solid" dose forms. One of ordinary skill in the relevant art could have had no reasonable expectation of producing solid compositions containing the levels of lipoic acid recited in the claims as amended. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Naylor*, 369 F.2d 765, 152 USPQ 106 (CCPA 1966); *Ex parte Old*, 229 USPQ 196 (BPAI 1985). See also MPEP § 2143.02.

In light of the foregoing amendments and remarks, it is believed that the examiner's rejections have been obviated and allowance of this application is respectfully requested.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

1. (currently amended) A solid formulation ~~based~~ comprising

   i) 10 to 30% of lipoic ~~on lipoid~~ acid or a physiologically acceptable salt thereof and, ~~where appropriate~~ optionally, other active substances

   and a formulation base having

   ii) a binder component; and

   iii) ~~where appropriate~~ optionally, other physiologically acceptable excipients,

   wherein ~~lipoid~~ lipoic acid or a physiologically acceptable salt thereof is in the form of a molecular dispersion.

2. (original) A formulation as claimed in claim 1, wherein at least one binder of the binder component is selected from polyvinylpyrrolidones, N-vinylpyrrolidone copolymers, cellulose derivatives and modified starches.

3. (currently amended) A formulation as claimed in claim 1, wherein the binder component has a glass transition temperature of more than 80°C ~~, preferably of more than 90° and in particular more than 100°~~.

4. (currently amended) A formulation as claimed in claim 1, wherein the formulation comprises

   i) ~~1 to 60% by weight, preferably 5 to 35% by weight and in particular~~ 10 to 30% by weight of active substance component;

   ii) ~~20 to 99% by weight, preferably 30 to 90% by weight and in particular~~ 40 to 80% by weight, of binder component;

iii) ~~0 to 91% by weight, preferably 1 to 60% by weight and in particular~~ 5 to 40% by weight, of other physiologically acceptable excipients~~;~~.

5. (currently amended) A formulation as claimed in claim 1, wherein the content of active substance component relative to binder component is from ~~1 to 50% by weight, preferably 10 to 40% by weight and in particular~~ 20 to 30% by weight.

6. (currently amended) A formulation as claimed in claim 1, comprising

i) ~~lipoid~~ lipoic acid or a physiologically acceptable salt thereof;

ii) at least one binder selected from polyvinylpyrrolidones, vinylpyrrolidone/vinyl acetate copolymers, hydroxypropyl-cellulose, hydroxypropylmethylcelluloses and modified starches; and

iii) ~~where appropriate other physiologically acceptable excipients, in particular~~ optionally a flow regulator ~~, e.g. highly disperse silica gel~~.

7. (currently amended) A formulation as claimed in claim 1 produced by melt extrusion of a mixture comprising ~~lipoid~~ lipoic acid or a physiologically acceptable salt thereof, binder and, ~~where appropriate~~ optionally, other active substances and/or other physiologically acceptable excipients.

8. (currently amended) A method for oral administration of ~~lipoid~~ lipoic acid or of a physiologically acceptable salt thereof, comprising administering a formulation as claimed in claim 1 ~~, where appropriate with the addition of other excipients as dosage form~~.

9. (new) A formulation as claimed in claim 3, wherein the binder component has a glass

transition temperature of more than 90°C.

10. (new) A formulation as claimed in claim 9, wherein the binder component has a glass transition temperature of more than 100°C.

11. (new) A formulation as claimed in claim 7, produced by thermal plastication in the absence of liquids or solvents.